

ABSTRACT

The present invention provides anticancer biological response modifier for the treatment of cancer. In accordance with an aspect of the present invention, there is provided a composition for the treatment of breast and prostate cancer in a mammal, said composition comprising small molecular weight components of less than 3000 daltons, and having the following properties: is extracted from bile of animals; is capable of stimulating monocytes and/or macrophages *in vitro* and/or *in vivo*; is capable of modulating tumor necrosis factor production and/or release; contains no measurable level of IL-1 α , IL-1 β , TNF, IL-6, IL-8, IL-4, GM-CSF or IFN-gamma; is not cytotoxic to human peripheral blood mononuclear cells; is not an endotoxin; and optionally with (ii) one or more anticancer agent(s), wherein said combination has therapeutic synergy or improves the therapeutic index in the treatment of cancer over the composition or the anticancer agent(s) alone. Another aspect of the present invention provides the use of this composition or combination in the manufacture of a medicament for the treatment of breast or prostate cancer in a mammal.